14

REC'D 05 SEP 2001

WIPO PCT

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BJN:MAR:FP13287	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU00/01039**	International Filing Date *(day/month/year)* 1 September 2000	Priority Date *(day/month/year)* 3 September 1999
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] C12Q 1/68, B65B 11/48, 11/50, B65D 65/46, 65/14, 75/30		
Applicant GENETIC SOLUTIONS PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of **12** sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
2 April 2001	24 August 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **JAGDISH BOKIL** Telephone No. (02) 6283 2371

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

[redacted]national application No.
PCT/AU00/01039

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-3, 6-7, 9, 11-17,** as originally filed,
pages , filed with the demand,
pages **4, 4/1, 5, 5/1, 8, 10,** received on **31 July 2001** with the letter of **30 July 2001**

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **18 - 23,** received on **31 July 2001** with the letter of **30 July 2001**

☒ the drawings, pages **1/2 - 2/2,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**1-32**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-32**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-32**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The claimed sampling collection device or system or method including the combination of features defined in the independent claims is not fairly suggested or taught by the prior art. Particularly, the tamperproofing features of the collection device, system or method eg. irreversible adhesive securement of the sheets for storage of the sample and the storage means being digestible for analysis, in claimed combinations are considered novel and inventive.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/01039

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: C12Q 1/68, B65B 11/48, 11/50, B65D 65/46, 65/14, 75/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: C12Q, B65B, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	WO 00/17396 A (I.D. GENE, INC. et al) 30 March 2000 figure i	1-5,7-8,11-13,15-28,31-38
Y, P		9-10,29-30
A, P	US 6007104 A (DRAPER) 28 December 1999 entire document	
Y, P	figures 1-2	9-10,29-30
X	JP 11166929 A (SEKISUI CHEM CO LTD) 22 June 1999 figures 1-3	1-14,20-22,28-38

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 October 2000	16 October 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer JAGDISH BOKIL Telephone No : (02) 6283 2371

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/01039

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5856102 A (BIERKE-NELSON et al) 5 January 1999 column 5 lines 28-39	1-3,20-22,38 15-19,23-27
Y	US 5432097 A (YOURNO) 11 July 1995 column 1 line 50- column 5 line 4	15-19,23-27
X	JP 10267761 A (NICHIYU GIKEN KOGYO KK) 9 October 1998 figures 1-3	1-14,20-22,28-38
X	US 3965888 A (BENDER) 29 June 1976 figures & corresponding description	1-14,20-22,28-38
A	US 5939259 A (HARVEY et al) 17 August 1999	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/01039

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member
US	6007104	NONE
JP	11166929	NONE
US	5856102	NONE
US	5432097	NONE
JP	10267761	NONE
US	3965888	NONE
US	5939259	NONE
WO	00/17396	NONE

END OF ANNEX

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference *(if desired) (12 characters maximum)* FP13287/BJN

Box No. I TITLE OF INVENTION

SAMPLING SYSTEM

Box No. II APPLICANT

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

GENETIC SOLUTIONS PTY LTD

50 Meiers Road
Indooroopilly, Queensland 4068
AUSTRALIA

☐ This person is also inventor.

Telephone No
+ 61-7 3214 2753

Facsimile No
+ 61-7 3214 2738

Teleprinter No.

State *(that is, country)* of nationality:
AUSTRALIA

State *(that is, country)* of residence:
AUSTRALIA

This person is applicant for the purposes of: ☐ all designated States ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

ARMITAGE, Sharon May

126 Banksia Circuit
Forest Lake, Queensland 4078
AUSTRALIA

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:
AUSTRALIA

State *(that is, country)* of residence:
AUSTRALIA

This person is applicant for the purposes of: ☐ all designated States ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicated in the Supplemental Box

☒ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

Griffith Hack
GPO Box 3125
Brisbane, Queensland 4001
AUSTRALIA

Telephone No
+ 61-7 3221 7200

Facsimile No
+ 61-7 3221 1245

Teleprinter No

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

BOWLER, Desmond Daryl

14 Quebec Avenue
Camp Hill, Queensland 4152
AUSTRALIA

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: AUSTRALIA

State *(that is, country)* of residence: AUSTRALIA

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

DAVIS, Gerard Peter

46 Orient Road
Yeronga, Queensland 4103
AUSTRALIA

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: AUSTRALIA

State *(that is, country)* of residence: AUSTRALIA

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

HETZEL, David James Stuart

28 Park Road West
Dutton Park Queensland 4102
AUSTRALIA

This person is:
- [ ] applicant only
- [X] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality: AUSTRALIA/US

State *(that is, country)* of residence: AUSTRALIA

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [X] the United States of America only
- [ ] the States indicated in the Supplemental Box

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)*

This person is:
- [ ] applicant only
- [ ] applicant and inventor
- [ ] inventor only *(If this check-box is marked, do not fill in below.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence

This person is applicant for the purposes of:
- [ ] all designated States
- [ ] all designated States except the United States of America
- [ ] the United States of America only
- [ ] the States indicated in the Supplemental Box

- [ ] Further applicants and/or (further) inventors are indicated on another continuation sheet

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes, at least one must be marked)*:

Regional Patent

[x] AP **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

[x] EA **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

[x] EP **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

[x] OA **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

[x] AE United Arab Emirates
[x] AL Albania
[x] AM Armenia
[x] AT Austria
[x] AU Australia
[x] AZ Azerbaijan
[x] BA Bosnia and Herzegovina
[x] BB Barbados
[x] BG Bulgaria
[x] BR Brazil
[x] BY Belarus
[x] CA Canada
[x] CH and LI Switzerland and Liechtenstein
[x] CN China
[x] CR Costa Rica
[x] CU Cuba
[x] CZ Czech Republic
[x] DE Germany
[x] DK Denmark
[x] DM Dominica
[x] EE Estonia
[x] ES Spain
[x] FI Finland
[x] GB United Kingdom
[x] GD Grenada
[x] GE Georgia
[x] GH Ghana
[x] GM Gambia
[x] HR Croatia
[x] HU Hungary
[x] ID Indonesia
[x] IL Israel
[x] IN India
[x] IS Iceland
[x] JP Japan
[x] KE Kenya
[x] KG Kyrgyzstan
[x] KP Democratic People's Republic of Korea
[x] KR Republic of Korea
[x] KZ Kazakhstan
[x] LC Saint Lucia
[x] LK Sri Lanka
[x] LR Liberia
[x] LS Lesotho
[x] LT Lithuania
[x] LU Luxembourg
[x] LV Latvia
[x] MA Morocco
[x] MD Republic of Moldova
[x] MG Madagascar
[x] MK The former Yugoslav Republic of Macedonia
[x] MN Mongolia
[x] MW Malawi
[x] MX Mexico
[x] NO Norway
[x] NZ New Zealand
[x] PL Poland
[x] PT Portugal
[x] RO Romania
[x] RU Russian Federation
[x] SD Sudan
[x] SE Sweden
[x] SG Singapore
[x] SI Slovenia
[x] SK Slovakia
[x] SL Sierra Leone
[x] TJ Tajikistan
[x] TM Turkmenistan
[x] TR Turkey
[x] TT Trinidad and Tobago
[x] TZ United Republic of Tanzania
[x] UA Ukraine
[x] UG Uganda
[x] US United States of America
[x] UZ Uzbekistan
[x] VN Viet Nam
[x] YU Yugoslavia
[x] ZA South Africa
[x] ZW Zimbabwe

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

[x] DZ Algeria
[x] AG Antigua and Barbuda

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM ☐ Further priority claim indicated in the Supplemental Box.

Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is: national application: country	regional application:* regional Office	international application: receiving Office
item (1) 3 Sept 1999 (03.09.1999)	PQ2658	Australia		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) *(only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office)* identified above as item(s). (1)

* *Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.*

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used)*: ISA /

Request to use results of earlier search; reference to that search *(if an earlier search has been carried out by or requested from the International Searching Authority)*: Date *(day/month/year)* | Number | Country *(or regional Office)*

Box No. VIII CHECK LIST; LANGUAGE OF FILING

This international application contains the following **number of sheets**:

request	:	4
description (excluding sequence listing part)	:	17
claims	:	6
abstract	:	1
drawings	:	2
sequence listing part of description	:	–
Total number of sheets	:	30

This international application is **accompanied by** the item(s) marked below:

1. ☐ fee calculation sheet
2. ☐ separate signed power of attorney
3. ☐ copy of general power of attorney; reference number, if any:
4. ☐ statement explaining lack of signature
5. ☐ priority document(s) identified in Box No. VI as item(s):
6. ☐ translation of international application into (language):
7. ☐ separate indications concerning deposited microorganism or other biological material
8. ☐ nucleotide and/or amino acid sequence listing in computer readable form
9. ☐ other *(specify)*:

Figure of the drawings which should accompany the abstract: 4

Language of filing of the international application: English

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

.....

Brendan John Nugent, Registered Patent Attorney of Griffith Hack for and on behalf of Genetic Solutions Pty Ltd, Sharon May Armitage, Desmond Daryl Bowler, Gerard Peter Davis and David James Stuart Hetzel.

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2).
5. International Searching Authority (if two or more are competent) ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid.

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

GRIFFITH HACK
GPO Box 3125
BRISBANE QLD 4001

PCT

WRITTEN OPINION

(PCT Rule 66)

	Date of mailing *(day/month/year)* 02 MAY 2001
Applicant's or agent's file reference BJN:MAR:FP13287	**REPLY DUE** within **TWO MONTHS** from the above date of mailing

International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU00/01039	1 September 2000	3 September 1999

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] C12Q 1/68, B65B 11/48, 11/50, B65D 65/46, 65/14, 75/30

Applicant

GENETIC SOLUTIONS PTY LTD et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:.

I	[X]	Basis of the opinion
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[X]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[X]	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **3 January 2002**

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**JAGDISH BOKIL** Telephone No. (02) 6283 2371

WRITTEN OPINION

International application No.
PCT/AU00/01039

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

- [X] the international application as originally filed.
- [ ] the description, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the claims, pages , as originally filed,
  pages , as amended under Article 19,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the drawings, pages , as originally filed,
  pages , filed with the demand,
  pages , received on with the letter of
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- [ ] contained in the international application in printed form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*

WRITTEN OPINION

International application No.
PCT/AU00/01039

V. **Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**15-19, 23-27**	**YES**
	Claims	**1-14, 20-22, 28-38**	**NO**
Inventive step (IS)	Claims	**15-19, 23-27**	**YES**
	Claims	**1-14, 20-22, 28-38**	**NO**
Industrial applicability (IA)	Claims	**1-38**	**YES**
	Claims		**NO**

2. Citations and explanations

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1- JP 11166929 A
D2- US 5856102 A
D3- JP 10267761 A
D4- US 3965888 A

Novelty (N) claims 1-14, 20-22, 28-38

D1- claims 1-6, 14, 20-22, 28, 36-38 (figures 1-3)
D2- claims 1-3, 20-22, 38 (column 5 lines 28-39)
D3- claims 1-14, 20-22, 28-38 (figures 1-3)
D4- claims 1-6, 14, 21, 28, 36-38 (the whole document)

The citations listed above disclose the features defined in the claims identified alongside (see the citation drawings and identified passages) e.g. D4 (see figure 5 & 8) clearly discloses the identified device and method claims.

Note: Claims 1 & 20 at least include within their scope a commonly used item or method - a non-reusable paper envelope or a storage method employing such an envelope.

Inventive Step (IS) claims 1-14, 20-22, 28-38

claims 1-14, 20-22, 28-38: as above

The invention defined in claims 7-13, 29-35 would furthermore be obvious to the person skilled in the art in the light of the disclosure of D1. The features added by the claims are well known in the art and their inclusion cannot be regarded as contributing an inventive step.

Novelty & Inventive Step claims 15-19, 23-27:

Upon reconsideration of the claim categorizations indicated in the international search report, I believe that the invention defined in claims 15-19, 23-27 is novel and involves an inventive step. The step of digesting a portion of the sample together with the storage means is not disclosed or fairly taught by the prior art identified hereinabove (but please refer to the next sheet of this opinion).

WRITTEN [redacted]NION

International application No.
PCT/AU00/01039

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date (valid claim) *(day/month/year)*
WO 00/17396 A	30 March 2000	22 September 1999	23 September 1998

This document is published later than the priority date of the current application. Subject to confirmation of the indicated citation priority date (23 September 1998), the document will possibly be at least relevant in countries where both the applications are being simultaneously processed. The citation unambiguously discloses (see e.g. page 11 lines 13-16 and pages 21-22) at least claims 1-4, 11, 13, 15-27, 37-38.

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure *(day/month/year)*	Date of written disclosure referring to non-written disclosure *(day/month/year)*

WRITTEN OPINION

International application No.
PCT/AU00/01039

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 1 is unclear in scope because the scope of the expression "suitable for digestion" at line 4 would depend upon the solvent used and is therefore indeterminate and not a real limitation. Similarly, the other independent claims also lack clarity.

The demand must be filed directly with the competent International Preliminary Examining Authority or, if more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority may be indicated by the applicant on the line below:

IPEA/ _____

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference: FP13287/BJN

International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/AU00/01039	1 September 2000 (01.09.00)	3 September 1999 (03.09.99)

Title of invention: GENETIC SOLUTIONS PTY LTD

Box No. II APPLICANT(S)

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

GENETIC SOLUTIONS PTY LTD

50 Meiers Road
Indooroopilly, Queensland 4068
AUSTRALIA

Telephone No.: + 61-7 3214 2753

Facsimile No.: + 61-7 3214 2738

Teleprinter No.:

State *(that is, country)* of nationality: AUSTRALIA

State *(that is, country)* of residence: AUSTRALIA

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

ARMITAGE, Sharon May

126 Banksia Circuit
Forest Lake, Queensland 4078
AUSTRALIA

State *(that is, country)* of nationality: AUSTRALIA

State *(that is, country)* of residence: AUSTRALIA

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

BOWLER, Desmond Daryl

14 Quebec Avenue
Camp Hill, Queensland 4152
AUSTRALIA

State *(that is, country)* of nationality: AUSTRALIA

State *(that is, country)* of residence: AUSTRALIA

[X] Further applicants are indicated on a continuation sheet

Sheet No. 2

International application No
PCT/AU00/01039

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet should not be included in the demand.

Name and address. *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code andname of country.)*

DAVIS, Gerard Peter

46 Orient Road
Yeronga, Queensland 4103
AUSTRALIA

State *(that is, country)* of nationality: AUSTRALIA

State *(that is, country)* of residence: AUSTRALIA

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code andname of country.)*

HETZEL, David James Stuart

28 Park Road West
Dutton Park, Queensland 4102
AUSTRALIA

State *(that is, country)* of nationality: AUSTRALIA/US

State *(that is, country)* of residence: AUSTRALIA

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code andname of country.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code andname of country.)*

State *(that is, country)* of nationality:

State *(that is, country)* of residence:

☐ Further applicants are indicated on another continuation sheet.

International application No. [redacted]/00/01039

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is [X] agent [ ] common representative

and [X] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[ ] is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

Griffith Hack
GPO Box 3125
Brisbane QLD 4001
AUSTRALIA

Telephone No.: 61 7 3221 7200

Facsimile No.: 61 7 3221 1245

Teleprinter No.:

[ ] **Address for correspondence:** Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special addr ess to which correspondence should be sent.

Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

1. The applicant wishes the international preliminary examination **to start on the basis of:**

[X] the international application as originally filed

the description
- [X] as originally filed
- [ ] as amended under Article 34

the claims
- [X] as originally filed
- [ ] as amended under Article 19 (together with any accompanying statement)
- [ ] as amended under Article 34

the drawings
- [X] as originally filed
- [ ] as amended under Article 34

2. [ ] The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. [ ] The applicant wishes the start of the international preliminary examination **to be postponed** until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

- [X] which is the language in which the international application was filed.
- [ ] which is the language of a translation furnished for the purposes of international search.
- [ ] which is the language of publication of the international application
- [ ] which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

Box No. V ELECTION OF STATES

The applicant hereby **elects all eligible States** *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes **not to elect:**

[redacted] Sheet No 4

International application No. [redacted]AU00/01039

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination.		For International Preliminary Examining Authority use only: received	not received
1. translation of international application	sheets	☐	☐
2. amendments under Article 34	sheets	☐	☐
3. copy (or, where required, translation) of amendments under Article 19	sheets	☐	☐
4. copy (or, where required, translation) of statement under Article 19	sheets	☐	☐
5. letter	sheets	☐	☐
6. other *(specify)*	sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. [X] fee calculation sheet
2. [ ] separate signed power of attorney
3. [ ] copy of general power of attorney; reference number, if any:
4. [ ] statement explaining lack of signature
5. [ ] nucleotide and or amino acid sequence listing in computer readable form
6. [ ] other *(specify)*:

Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

Brendan John Nugent
Registered Patent Attorney
for and on behalf of
GRIFFITH HACK

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:
2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):
3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. ☐ The applicant has been informed accordingly.
4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82

For International Bureau use only

Demand received from IPEA on

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BJN:MAR:FP13287	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU00/01039**	International Filing Date *(day/month/year)* 1 September 2000	Priority Date *(day/month/year)* 3 September 1999
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] C12Q 1/68, B65B 11/48, 11/50, B65D 65/46, 65/14, 75/30		
Applicant GENETIC SOLUTIONS PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of **12** sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand 2 April 2001	Date of completion of the report 24 August 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **JAGDISH BOKIL** Telephone No. (02) 6283 2371

INTERNATIONAL PRELIMIN[redacted]EXAMINATION REPORT

I[redacted]tional application No.
PCT/AU00/01039

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **1-3, 6-7, 9, 11-17,** as originally filed,
pages , filed with the demand,
pages **4, 4/1, 5, 5/1, 8, 10,** received on **31 July 2001** with the letter of **30 July 2001**

☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **18 - 23,** received on **31 July 2001** with the letter of **30 July 2001**

☒ the drawings, pages **1/2 - 2/2,** as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

INTERNATIONAL PRELIMI[redacted]EXAMINATION REPORT

[redacted]national application No.
PCT/AU00/01039

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-32	YES
	Claims		NO
Inventive step (IS)	Claims	1-32	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The claimed sampling collection device or system or method including the combination of features defined in the independent claims is not fairly suggested or taught by the prior art. Particularly, the tamperproofing features of the collection device, system or method eg. irreversible adhesive securement of the sheets for storage of the sample and the storage means being digestible for analysis, in claimed combinations are considered novel and inventive.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 15 May 2001 (15.05.01)	
International application No. PCT/AU00/01039	**Applicant's or agent's file reference** FP13287/BJN
International filing date (day/month/year) 01 September 2000 (01.09.00)	**Priority date** (day/month/year) 03 September 1999 (03.09.99)
Applicant ARMITAGE, Sharon, May et al	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   02 April 2001 (02.04.01)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Claudio Borton
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 March 2001 (15.03.2001)

PCT

(10) International Publication Number
WO 01/18239 A1

(51) International Patent Classification[7]: C12Q 1/68, B65B 11/48, 11/50, B65D 65/46, 65/14, 75/30

(21) International Application Number: PCT/AU00/01039

(22) International Filing Date:
1 September 2000 (01.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PQ 2658 3 September 1999 (03.09.1999) AU

(71) Applicant *(for all designated States except US)*: **GENETIC SOLUTIONS PTY LTD** [AU/AU]; 50 Meiers Road, Indooroopilly, Queensland 4068 (AU).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ARMITAGE, Sharon, May** [AU/AU]; 126 Banksia Circuit, Forest Lake, Queensland 4078 (AU). **BOWLER, Desmond, Daryl** [AU/AU]; 14 Quebec Avenue, Camp Hill, Queensland 4152 (AU). **DAVIS, Gerard, Peter** [AU/AU]; 46 Orient Road, Yeronga, Queensland 4103 (AU). **HETZEL, David, James, Stuart** [AU/AU]; 28 Park Road West, Dutton Park, Queensland 4102 (AU).

(74) Agent: **GRIFFITH HACK**; GPO Box 3125, Brisbane, Queensland 4001 (AU).

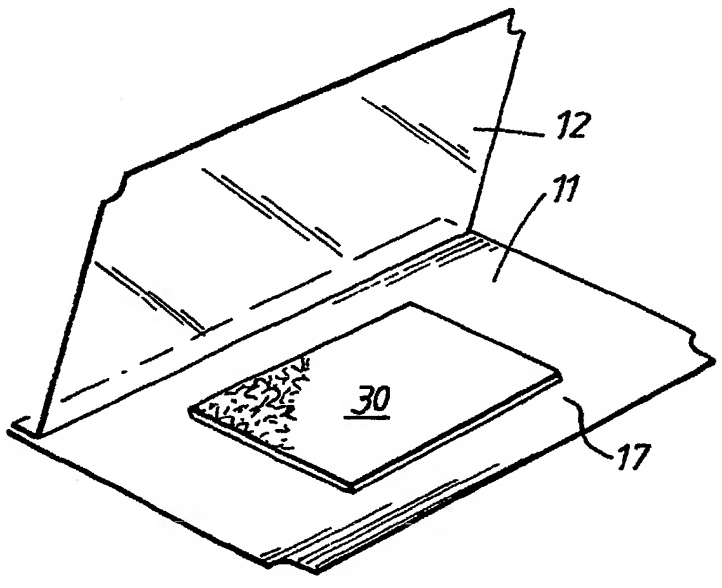
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SAMPLING SYSTEM



(57) Abstract: A device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample.

WO 01/18239 A1

SAMPLING SYSTEM

TECHNICAL FIELD

The present invention is concerned with a sampling system and, more particularly, with a sampling system for the storage of biological samples for subsequent analysis.

BACKGROUND ART

Biological samples are frequently collected in the field for later analysis for a variety of purposes. The analysis to be conducted will often be an analysis of the DNA contained in the sample in order to establish the genetic profile of the sample. Such an analysis may be conducted, for example, to verify and/or trace genetic lines in stock, to identify desirable traits in animals by identifying genetic markers for these traits or to identify the source of animal or plant material in a food product. For example, meat and meat products may be traced using DNA analysis in order to ensure that substitution of a lesser quality product has not occurred at any stage in the processing of the meat product or to identify the source of meat found to be contaminated in the marketplace.

DNA analysis for the purpose of identifying an individual organism is a well-known technique. For example, United States Patent No. 5,211,286, United States Patent No. 5,101,970 and United States Patent No. 5,856,102 describe systems for the identification of individual human beings in this way. In each case the invention is concerned with a personal identification system in which DNA-containing samples such as hair are stored in sealable plastic envelopes in a person's home to assist in their identification should the person become lost or go missing. However, each of these samples relies on the goodwill of those handling the DNA-containing materials prior to undertaking the analysis to ensure the

integrity of the sample, since there is no means of avoiding tampering in the system or substitution of alternative samples. Accordingly, the only use for such systems is for an individual to store samples of their own DNA-containing material where they have control of that sample, such as in the family freezer.

Attempts have been made to ensure that the identity of meat and meat products can be traced through the production process in a variety of ways. For example, the identity of beef, pigs and poultry on a batch or consignment basis is sometimes recorded using batch/consignment numbers applied to the batch/consignment source through the slaughter process to the consumer. Indeed, in some countries e.g. the United Kingdom, Government agencies issue numeric or alpha-numeric codes to farmers who subsequently allocate such codes to each of the animals bred by them. The allocated codes are generally inscribed on ear-tags applied to the animal and recorded on a card peculiar to the animal to allow for unique identification of that animal. Various other data on an animal may also be recorded, such as the vaccination records of the animal. The information can be forwarded to a Government agency progressively or at some time just prior to slaughter of the animal. Nevertheless, this system is administratively intensive and the identification and testing records are not easily integrated.

In the slaughter process a beast is often divided at an early stage, and then sub-codes identifying each half of the beast are generated and continue to be used to identify the halves. However, further division occurs later in the butchering process, at which point it becomes impractical to continue to assign codes to each batch of meat. Accordingly, although attempts have been made to continue to identify meat using tags or labels all the way through the process, it is difficult to ensure that such tags and labels are applied accurately. Therefore, the

information provided in such systems may be inaccurate and the systems are highly labour intensive and expensive. Accordingly, meat and meat products will frequently be retailed without any identification tag or label able to trace the product through the slaughter process back to the beast from which it originated.

International Application No. PCT/IE98/00021 describes a method for identifying the animal from which a meat product is derived, comprising genotyping the meat, comparing the genotype with known animal genotypes and locating any matching genotype to identify the animal from which the meat product is derived. The application of this method requires that DNA analysis be conducted of all animals and the data stored and then matched to any meat products tested. Alternatively, the samples from such beasts can be stored and then analysed later if the need arises. In either case, a library of genetic information of beasts is built up and compared to the DNA profile of meat analysed, either for routine quality assurance purposes (to trace product history to ensure, for example, that substitution of an inferior quality meat has not occurred) or, in instances where contamination of meat has been identified, so that the meat may be traced back to the trade source in an effort to identify the cause of the contamination.

The sampling system proposed in PCT/IE98/00021 is to take samples from animals in the conventional manner and then place them in an identification tube or cell which is marked with the animal tag identification code, but not secured in any way. The sample is then transferred to a laboratory for PCR analysis. The labeled tube or cell is placed in a well of a microtitre plate having a multiplicity of such wells, with each well being provided with a code matching the animal tag identification code. The analysis is conducted in the marked microtitre plate but there is no way of ensuring, aside from matching the codes manually, that the correct

identification tube or cell is placed in the correct well in the microtitre plate. Thus, if only the code from the microtitre plate is used for subsequent identification, errors can occur. However, of still greater concern is the possibility that samples may be switched from one identification tube or cell to another long before such cells or tubes reach the laboratory where the analysis is conducted, since the tubes or cells are not secured. Accordingly, if a person with fraudulent intent chooses to substitute one sample for another in the samples provided for DNA analysis, this substitution will not be detectable. The present invention seeks to provide a way of ensuring that the identity of a biological sample is known with certainty when an analysis of the sample is conducted.

DISCLOSURE OF THE INVENTION

According to a first aspect of the present invention, there is provided a device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample.

According to a second aspect of the present invention, there is provided a system for the analysis of a biological sample, comprising:

a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis;

means for taking at least a portion of said sample for analysis together with at least the part of said storage means in which it is encased;

means for digesting said sample, or portion thereof, together with at least said part of said storage means; and

means for analysing said sample.

According to a third aspect of the present invention, there is provided a method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample; and

storing said sample in said storage means.

According to a fourth aspect of the invention, there is provided a method of analysing a biological sample, comprising the steps of:

providing a device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample;

taking at least a portion of said sample together with at least the part of said storage means in which it is encased;

digesting said sample, or portion thereof, together with at least said part of said storage means; and

analysing said sample.

Preferably, the device comprises sheets of material suitable for digestion together with said biological sample, between which said biological sample is stored.

Typically these sheets are adapted to be substantially irreversibly adhered together.

In a particularly preferred form of the invention, a cover sheet is adapted to be substantially irreversibly adhered to a base sheet arranged so that the biological sample may be positioned thereon. The cover sheet may be hingedly secured to the base sheet. In particular, the cover sheet may be coated with a permanent adhesive across its entire surface, and the portion of the

cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet. A backing sheet is generally releasably secured to the surface of the cover sheet in order to prevent it sticking to the base sheet before it is put to use in collecting a biological sample.

Advantageously said base sheet is printed on its reverse. A bar code may be printed on this sheet together with instructions for use of the device and/or an area to write an identification code.

Advantageously, the base sheet is a sheet of paper, typically a sheet of gloss art paper. The cover sheet is typically a clear polypropylene film and the backing sheet is a release paper.

The biological sample may be any suitable body part including animal hair, hide, buccal swabs, blood, muscle, bone, scales or the organs of an animal, or may be plant material such as leaves, stems or woody material. Body fluids including blood, saliva, semen and urine may also be sampled.

Preferably the sample is subjected to analysis to establish a DNA profile, but the analysis may be for any material contained in said sample provided that it is present in sufficient quantities for the analysis and that none of the materials in said storage means interferes with the analysis. For example, the sample may be analysed for protein or mineral content, or for the content of other materials such as carbohydrate or lipid. It may also be analysed for the presence of chemicals such as chemical contaminants e.g. pesticides in the sample. Typically, the analysis comprises amplification of the DNA contained in a sample such as animal hair using the polymerase chain reaction (PCR) followed by DNA sequencing to establish a genetic profile. The purpose of the analysis used, for example, to verify and/or trace genetic lines in stock, to identify desirable traits in animals by identifying genetic markers for these traits or to

identify the source of animal or plant material in a food product. In particular, meat and meat products may be traced using DNA analysis in order to ensure that substitution of a lesser quality product has not occurred at any stage in the processing of the meat product or to identify the source of meat found to be contaminated in the marketplace.

Typically, the sample is taken for analysis by punching out at least a portion of the sample that has been collected together with that part of said storage means in which it is encased, using a conventional punching device. It will be appreciated that contamination of the sample cannot occur in this process, as may occur, for example, if a sample is transferred from one vessel to another for analysis. Moreover, the integrity of the sample is ensured since there is no possibility of accidental switching of the sample at this stage.

The sample together with the part of said storage means is digested by conventional means for analysis. In the case of DNA for PCR analysis, this may be by a conventional alkali extraction or phenol/chloroform extraction. In this step, the material making up said storage means may dissolve or partially dissolve, but at least should not interfere with development of the DNA profile.

In a particularly preferred embodiment of the invention, the device also bears a code corresponding to or linked to the animal tag identification code. This means that the sample from the animal is identified at the point of taking the sample by the same unique identifier or a different unique identifier provided the two are linked as the animal, and this unique identifier remains in physical juxtaposition with the biological sample from the time it is taken to the time the sample is analysed. Given that the storage means is tamper-evident, any tampering after collection, for example when a sample is

archived, will be readily apparent to the person analysing the sample.

According to a fifth aspect of the present invention, there is provided a device for collecting and storing a biological sample for subsequent analysis, comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

Typically said base sheet is adapted for a biological sample to be positioned on a first surface and has printing identifying the sample on a second surface. Typically the printing is a bar-code which encodes the animal tag identification code or the animal identification code itself. In the latter case, the code may be written into an appropriate space by the person taking the sample. Typically, the second surface also includes information as to how to use the sample collection device.

The base sheet is typically a substantially rectangular sheet of paper, hence the first surface is the obverse of said base sheet and the second surface is its reverse. Preferably, the base sheet is a gloss art paper to ensure strong adhesion, and it should not contain any chemicals which will inhibit or interfere with the analysis to be conducted. Typically it is a sheet of 150gsm A2 gloss art paper

Each substantially rectangular base sheet may be joined by a line of weakness to a substantially identical sheet in order to connect a plurality of devices in accordance with the present invention. This allows the devices to be provided to the user as a roll from which

individual sample storage devices may be torn off. The cover sheet may also be joined to adjacent cover sheets by a line of weakness, in which case separation of the cover sheet from the adjacent cover sheet is also necessary in order to remove an individual sample storage device. Alternatively, although it is not preferred, only the cover sheet may be connected to adjacent cover sheet by a line of weakness.

The base sheet and the cover sheet also include an elliptical bite taken therefrom which makes it easier for the backing sheet to be removed from the cover sheet, and is also useful in lining up rolls of individual sample storage devices during printing of the roll. The cover sheet may be hingedly secured to the base sheet in any convenient manner, but is typically secured thereto through adhesive securement along a line adjacent an edge of the base sheet. The adhesive securement may be along the entire length of said first edge or along a portion of said edge.

Typically, the cover sheet is coated across its entire surface with a permanent adhesive and the backing sheet is applied to that portion of the cover sheet which is intended to encase the biological sample. The remainder of the cover sheet then adheres to the base sheet in order to hingedly secure it thereto.

The cover sheet is typically a polymeric film, preferably a clear polypropylene film.

The adhesive may be any suitable adhesive, and is typically a pressure-sensitive adhesive. It should contain no animal products so as not to introduce any foreign DNA into the analysis process.

The backing sheet is typically a release paper. In use, when the backing sheet is peeled from the cover sheet, the adhesive on the cover sheet bonds firmly and substantially irreversibly to said base sheet. Any efforts to peel the cover sheet from the base sheet would typically result in destruction of the base sheet and/or

the cover sheet, or at least in sufficient mutilation of the two for the attempt to tamper with a sample to be apparent.

An absorbent material may be secured on the front surface of said base sheet. This makes collection of body fluids easier as a quantity of these may be absorbed by the absorbent layer. Typically the absorbent layer is blotting paper.

According to a sixth aspect of the present invention, there is provided a method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

removing said backing sheet; and

allowing said cover sheet to adhere substantially irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

Devices in accordance with the present invention may also be supplied together with a sampling device for sampling animal tissue.

Accordingly in a seventh aspect of the present invention, there is provided a kit comprising a sample collection device as described above together with a sampling device.

The sampling device preferably takes a consistent and reproducible sample from animals whilst simultaneously avoiding any cross-contamination of tissue. The nature of the sampling device will be well understood by the person skilled in the art, but is typically forceps or pliers. The kit may also include instructions for use of the sample collection device.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

FIG. 1 is a bottom plan view of a device for storing a biological sample in accordance with the present invention;

FIG. 2 is a cross-section through a device for storing a biological sample in accordance with the present invention;

FIG. 3a is a flowchart illustrating the manner in which a device for storage of a biological sample in accordance with the present invention is prepared for use;

FIG. 3b is a flowchart illustrating the subsequent application of a biological sample to said device;

FIG. 3c is a flowchart illustrating the manner in which a portion of said sample is taken for analysis; and

FIG. 4 shows a device for storing a sample of a body fluid in accordance with the present invention.

BEST MODE FOR CARRYING OUT THE INVENTION

A sample storage device 10 in accordance with the present invention, as best seen in FIG. 2 and the first frame of FIG. 3a, comprises a base sheet 11 arranged so that the biological sample may be positioned thereon, a cover sheet 12 hingedly secured to the base sheet 11 and having a backing sheet 13 releasably secured thereto. The base sheet 11 is printed on its reverse 14, which contains a bar-code 15 and also a space for writing an animal tag identification code where the sampler does not have facilities for reading a bar-code. In addition, the reverse 14 of the base sheet 11 contains instructions for use of the device, as will be discussed below in relation to FIG.s 3a-3c. The base sheet 11 is a sheet of 150 gsm A2 gloss art paper adapted to receive a biological sample on its obverse surface 17, as best seen in the first frame

of FIG. 3b, where a biological sample 18 has been deposited thereon. It also adheres substantially irreversibly to the cover sheet 12 when the backing sheet 13 is removed therefrom and the two are brought together.

As best seen in FIG. 3a, the cover sheet 12 is hingedly secured to the base sheet 11. In fact, the surface 19 of the cover sheet 12 facing base sheet 11 is completely covered with adhesive and backing sheet 13 is releasably secured over a portion only of the cover sheet 12. It will be appreciated that backing sheet 13 is made of a release paper and so can be easily peeled off cover sheet 12, but the adhesive on cover sheet 12 bonds substantially irreversibly to base sheet 11. This means that the portion of the cover sheet 12 which is not covered by backing sheet 13 bonds strongly to base sheet 11. Accordingly, by leaving a region of cover sheet 12 uncovered by backing sheet 13, the cover sheet 12 can be hingedly secured to base sheet 11. In this case, the backing sheet 13 is substantially rectangular in shape and corresponds in size to the size of the cover sheet 12, which is also substantially rectangular in shape, except that the length of sides 20, 21 is slightly lesser than the sides 22, 23 of cover sheet 12. Hence a small portion of cover sheet 12 adjacent an edge is left exposed, and so adheres to base sheet 11 to form a hinged connection along line 24.

As best seen in FIG. 4, a square of blotting paper 30 may be bonded to the obverse surface 17 of the base sheet 11. Samples of body fluids such as blood, saliva, semen and urine may be deposited on the blotting paper and will be absorbed.

In use, a person taking a biological sample would read the instructions on the reverse 14 of the base sheet 11 and follow these. Accordingly, that person would be directed to peel back the backing sheet 13 in the manner shown in FIG. 3a and so expose the adhesive on cover sheet 12. This person would then place biological sample 18

centrally on the obverse surface 17 of base sheet 11 and allow the cover sheet 13 to collapse onto the biological sample 18 and base sheet 11 so as to adhere to them. This is best seen in FIG. 3b. Having done this, the biological sample can be archived or sent immediately for analysis. At all times, the bar-code or animal tag identification code written on the back is in physical juxtaposition with the sample, which is encased in the sample storage device 10. If one were to attempt to remove the sample by peeling back cover sheet 13 from base sheet 11 damage to one or both sheets would occur, and the attempt to tamper with the integrity of the sample would be noted by a person subsequently conducting an analysis of the sample.

When analysis of the sample is to be conducted, a punch 25 is employed to punch a hole through the centre of biological sample 18 to create sub-sample 26. It will be appreciated that the punch removes the biological sample together with those portions of both the base sheet 11 and cover sheet 13 which encase it. The biological sample 18 does not need to be removed from the sample storage device 10 prior to analysis, hence the possibility of cross-contamination is minimised and the opportunity for tampering with the sample or substitution with another sample is limited even at the analysis stage. The sub-sample 26 that is punched out will immediately be placed in an appropriate vessel for digestion and subsequent analysis in the conventional manner.

The results of the analysis can then be matched to the animal tag identification code and/or bar-code to add to the information compiled on the beast from which the sample came. This allows for unequivocal identification of the genetic identity of the beast and so allows for comparison of a subsequent DNA analysis of a meat sample with these records to identify the source of any single piece of meat. In turn, this allows an audit line to be established to ensure that substitution of meat or meat products has not occurred and allows a source of

contamination to be identified through tracing the contaminated meat back through the slaughter process to a particular beast.

The results of the analysis may also be used to verify and/or trace genetic lines in stock. Thus, the purported blood line of an animal may be checked by comparing the DNA profile compiled for the animal to the records established for other animals. Where the particular animal tested has a desirable trait, the results of the test may be used to identify genetic markers for this trait. Thereafter, animals bearing this genetic marker may be selected for when breeding in an endeavour to establish the desirable trait widely within a breed.

Alternatively, the analysis may be a chemical analysis to establish the composition of the biological sample. For example, the sample may be analysed for protein or mineral content, or for the content of other materials such as carbohydrate or lipid. The analysis may also be for the presence of chemicals such as chemical contaminants. For example, the presence of trace levels of pesticides in a sample can be detected and then the contamination traced back to its source.

EXAMPLE 1

A biological sample collected and stored in accordance with the present invention may then be subjected to PCR analysis to obtain a DNA profile using the following method:

Alkali Extraction Method

A hole is punched through the centre of a sample storage device in accordance with the present invention in the region where the biological sample is located. Thus, a sub-sample is created which contains a portion of the biological sample together with that part of the sample storage device in which it is encased. This material is

then placed in a 0.2µl tube or well of a 96 well microtitre plate. The tube or plate is centrifuged briefly so that the sub-sample collects into the bottom of the tube or a well of the plate. 50µl of a 200mM sodium hydroxide solution is added and the mixture is incubated at 95°C for minutes. The contents of the tube or well are mixed two to three times during the incubation by quickly removing the tube or plate from the heating block and tapping several times. The mixture is then briefly centrifuged to bring down any condensation on the lids of the tube or plate. Thereafter, 50µl of a solution containing 200mM HCl, 100mM Tris.HCl, pH 8.5 is added and the mixture mixed briefly prior to centrifuging for two minutes at 13000rpm. In the next step, 80µl of the supernatant is transferred to a fresh tube/plate and diluted with 100µl sterile MilliQ H_2O. The solution is stored at -20°C for subsequent use of 1-2µl in PCR.

Amplification and Analysis

The PCR techniques employed are conventional, and well understood by the person skilled in the art. Generally, the process involves a repetitive series of thermal cycles involving template denaturation, primer annealing and extension of the annealed primers by Taq DNA polymerase, with the result that there is an exponential accumulation of specific short DNA sequences. These DNA sequences are characteristic of the beast from which the sample was taken, and typically contain length variation at DNA sequence repeats or microsatellites which allow identification of the beast. In particular, microsatellite loci peculiar to the species of animal being tested can be amplified and analysed using the PCR process. Suitable primers are well known and, for example, are contained in the cattle paternity bovine PCR typing kit sold by Perkin Elmer under the name STOCKMARKS. This kit incorporates fluorescent tagged primers specific to eleven microsatellite loci useful in identifying cattle

as well as unlabeled primers, polymerase, reference bovine DNA, dNTPs and buffers necessary to test the animals at these loci. The kit describes the procedures for conducting the analysis which are, in any event, well understood by the person skilled in the art.

The amplified product may then be subjected to a DNA fragment analysis on a suitable DNA analysis system, the likes of which are commercially available. The DNA profiles thus obtained are unique and unequivocally linked to the beast from which the sample is obtained through the audit trail described above. The genetic profile of a tissue sample subsequently obtained can be searched on a database of these genetic profiles to locate a match. Therefore, the original animal from which a tissue sample derived can be identified.

Throughout this specification and the claims, the words "comprise", "comprises" and "comprising" are used in a non-exclusive sense, except where the context requires otherwise.

Variations and modifications of this device will be apparent to the person skilled in the art, and those variations and modifications are within the scope of the present invention.

INDUSTRIAL APPLICABILITY

The present invention ensures the integrity of biological samples taken in the field and analysed subsequently in a laboratory. Thus analysis of the samples may be conducted in order to establish a genetic profile of the sample or to ascertain its composition with the assurance that the sample has not been tampered with or modified in transit. This means that an analysis to verify and/or trace genetic lines in stock, to identify desirable traits in animals by identifying genetic markers for those traits or to identify the source of animal or plant material in a food product can be done with assurance that the results are accurate. Likewise, the

samples may be analysed for a protein or mineral content, or for the content of other materials such as carbohydrate or lipid and the results may be assured. In particular, it may be analysed for the presence of chemical contaminants with the assurance that the sample has not been modified in any way in transit.

CLAIMS

1. A device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample.

2. A device as claimed in claim 1 wherein said storage means comprises sheets of material suitable for digestion together with said biological sample, between which said biological sample is stored.

3. A device as claimed in claim 2 wherein said sheets are adapted to be substantially irreversibly adhered together.

4. A device as claimed in claim 3 wherein a cover sheet is adapted to be substantially irreversibly adhered to a base sheet arranged so that the biological sample may be positioned thereon.

5. A device as claimed in claim 4 wherein the cover sheet is hingedly secured to said base sheet.

6. A device as claimed in claim 5, further comprising a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

7. A device as claimed in claim 6 wherein the cover sheet is coated with a permanent adhesive across its entire surface, and the portion of the cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet.

8. A device as claimed in claim 7 wherein the adhesive is a pressure-sensitive adhesive.

9. A device as claimed in any one of claims 4 to 8 wherein said base sheet is printed on its reverse

10. A device as claimed in claim 9 wherein a bar code is printed on the reverse of said base sheet.

11. A device as claimed in any one of claims 4 to 10 wherein the base sheet is a sheet of paper.

12. A device as claimed in claim 11 wherein the base sheet is a sheet of gloss art paper.

13. A device as claimed in any one of claims 4 to 12 wherein the cover sheet is a clear polypropylene film.

14. A device as claimed in any one of claims of 6 to 13 wherein the backing sheet is a release paper.

15. A system for the analysis of a biological sample, comprising:

a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis;

means for taking at least a portion of said sample for analysis together with at least the part of said storage means in which it is encased;

means for digesting said sample, or portion thereof, together with at least said part of said storage means; and

means for analysing said sample.

16. A system as claimed in claim 15 wherein the device is a device as defined in any one of claims 1 to 14.

17. A system as claimed in claim 15 or claim 16 wherein a hole punch takes a portion of said sample for analysis together with that part of the storage means in which it is encased.

18. A system as claimed in any one of claims 15 to 17 wherein said sample is digested in an alkali extraction.

19. A system as claimed in any one of claims 15 to 18 wherein said sample is subjected to amplification by PCR and then DNA sequencing.

20. A method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample; and

storing said sample in said storage means.

21. A method as claimed in claim 20 wherein the device is a device as defined in any one of claims 1 to 14.

22. A method as claimed in claim 20 or claim 21 wherein said biological sample is stored for an extended period of time.

23. A method of analysing a biological sample, comprising the steps of:

providing a device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample;

taking at least a portion of said sample together with at least the part of said storage means in which it is encased;

digesting said sample, or portion thereof, together with at least said part of said storage means; and

analysing said sample.

24. A method as claimed in claim 23 wherein the device is a device as defined in any one of claims 1 to 14.

25. A method as claimed in claim 23 or claim 24 wherein a portion of said sample is punched out of the device with a hole punch.

26. A method as claimed in any one of claims 23 to 25 wherein said sample is digested in an alkali extraction.

27. A method according to any one of claims 23 to 26 wherein said sample is subjected to amplification by PCR and then DNA sequencing.

28. A device for collecting and storing a biological sample for subsequent analysis, comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

29. A device as claimed in claim 28 wherein said base sheet is printed on its reverse.

30. A device as claimed in claim 28 wherein a bar code is printed on the reverse of said base sheet.

31. A device as claimed in any one of claims 28 to 30 wherein the base sheet is a sheet of paper.

32. A device as claimed in claim 31 wherein the base sheet is a gloss art paper.

33. A device as claimed in any one of claims 28 to 32 wherein the cover sheet is coated with a permanent adhesive across its entire surface, and the portion of the cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet.

34. A device as claimed in claim 33 wherein the adhesive is a pressure-sensitive adhesive.

35. A device as claimed in any one of claims 28 to 34 wherein the cover sheet is a clear polypropylene film.

36. A device as claimed in any one of claims of 28 to 35 wherein the backing sheet is a release paper.

37. A method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

removing said backing sheet; and

allowing said cover sheet to adhere substantially irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

38. A kit comprising a sample collection device as defined in any one of claims 1 to 14 and a sampling device for collecting a biological sample.

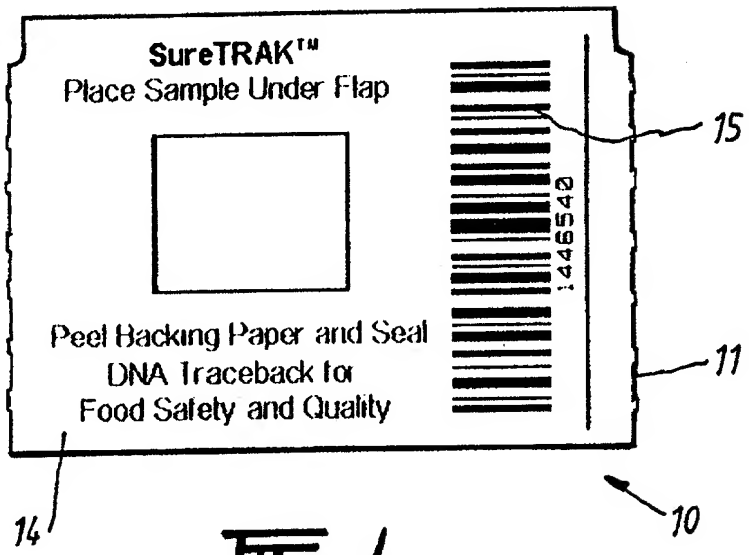


FIG. 1.

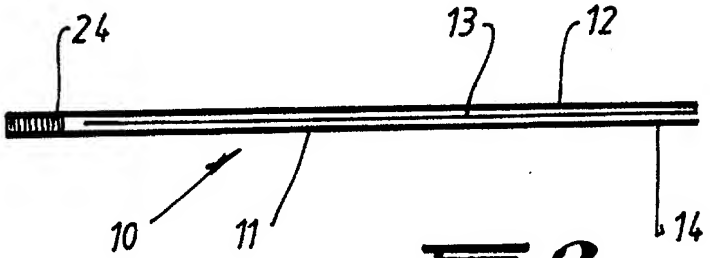
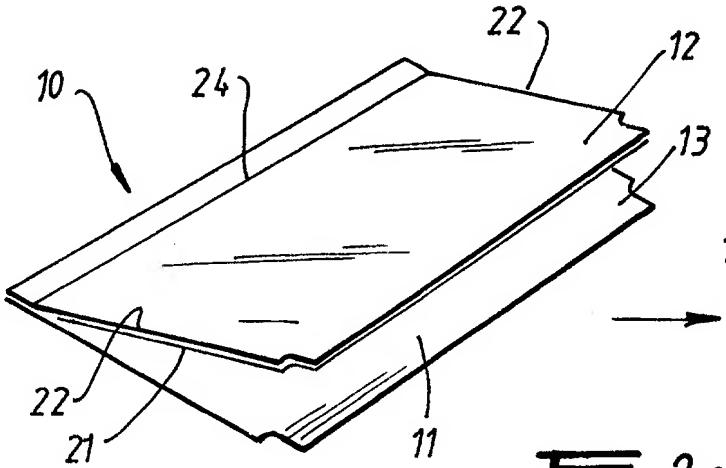


FIG. 2.



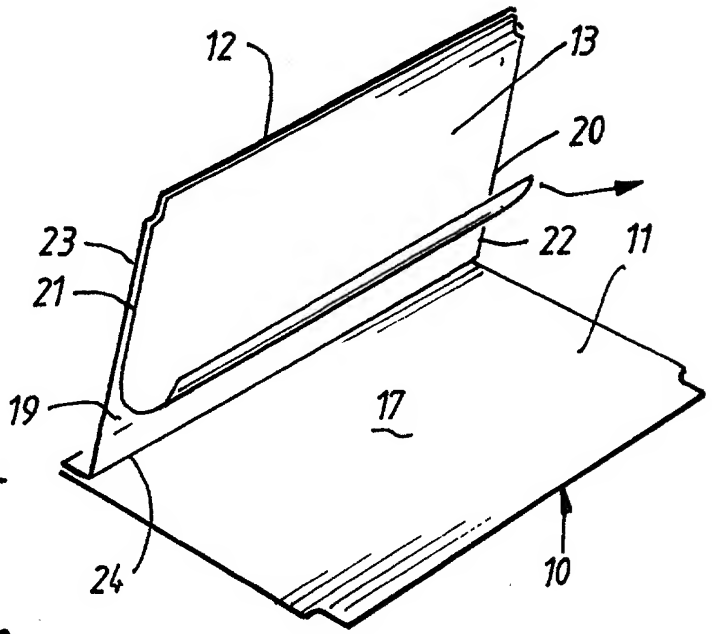


FIG. 3a.

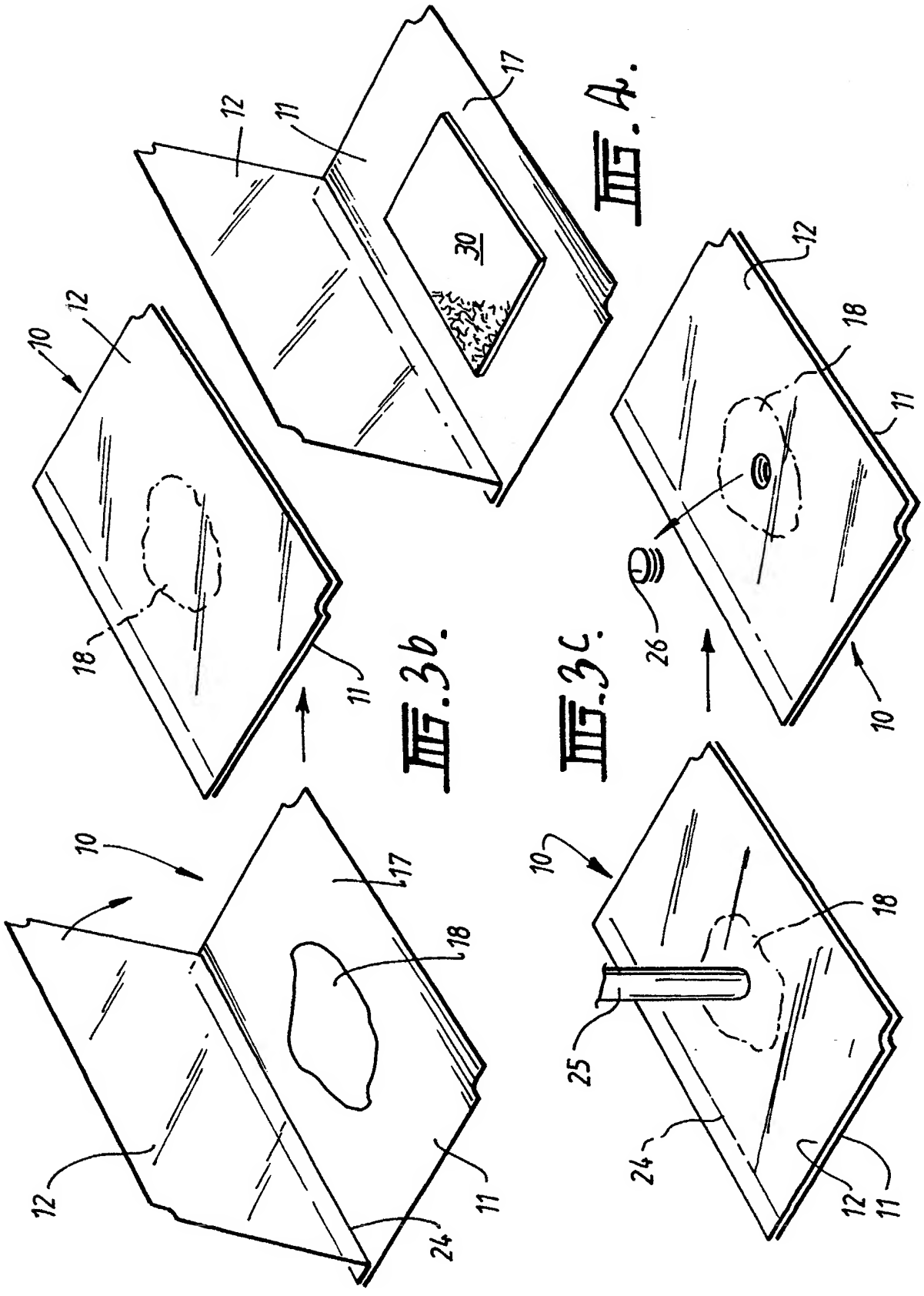


Fig. 3b.

Fig. 3c.

Fig. 4.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/01039

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: C12Q 1/68, B65B 11/48, 11/50, B65D 65/46, 65/14, 75/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: C12Q, B65B, B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	WO 00/17396 A (I.D. GENE, INC. et al) 30 March 2000 figure i	1-5,7-8,11-13,15-28,31-38
Y, P		9-10,29-30
A, P	US 6007104 A (DRAPER) 28 December 1999 entire document	
Y, P	figures 1-2	9-10,29-30
X	JP 11166929 A (SEKISUI CHEM CO LTD) 22 June 1999 figures 1-3	1-14,20-22,28-38

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 October 2000	16 October 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer **JAGDISH BOKIL** Telephone No : (02) 6283 2371

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/01039

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5856102 A (BIERKE-NELSON et al) 5 January 1999 column 5 lines 28-39	1-3,20-22,38 15-19,23-27
Y	US 5432097 A (YOURNO) 11 July 1995 column 1 line 50- column 5 line 4	15-19,23-27
X	JP 10267761 A (NICHIYU GIKEN KOGYO KK) 9 October 1998 figures 1-3	1-14,20-22,28-38
X	US 3965888 A (BENDER) 29 June 1976 figures & corresponding description	1-14,20-22,28-38
A	US 5939259 A (HARVEY et al) 17 August 1999	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/01039

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member
US	6007104	NONE
JP	11166929	NONE
US	5856102	NONE
US	5432097	NONE
JP	10267761	NONE
US	3965888	NONE
US	5939259	NONE
WO	00/17396	NONE

END OF ANNEX

identification tube or cell is placed in the correct well in the microtitre plate. Thus, if only the code from the microtitre plate is used for subsequent identification, errors can occur. However, of still greater concern is the possibility that samples may be switched from one identification tube or cell to another long before such cells or tubes reach the laboratory where the analysis is conducted, since the tubes or cells are not secured. Accordingly, if a person with fraudulent intent chooses to substitute one sample for another in the samples provided for DNA analysis, this substitution will not be detectable. The present invention seeks to provide a way of ensuring that the identity of a biological sample is known with certainty when an analysis of the sample is conducted.

DISCLOSURE OF THE INVENTION

According to a first aspect of the present invention, there is provided a device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample.

According to a second aspect of the present invention, there is provided a system for the analysis of a biological sample, comprising:

a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis;

means for taking at least a portion of said sample for analysis together with at least the part of said storage means in which it is encased;

means for digesting said sample, or portion thereof, together with at least said part of said storage means; and

means for analysing said sample.

According to a third aspect of the present invention, there is provided a method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample; and

storing said sample in said storage means.

According to a fourth aspect of the invention, there is provided a method of analysing a biological sample, comprising the steps of:

providing a device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample;

taking at least a portion of said sample together with at least the part of said storage means in which it is encased;

digesting said sample, or portion thereof, together with at least said part of said storage means; and

analysing said sample.

Preferably, the device comprises sheets of material suitable for digestion together with said biological sample, between which said biological sample is stored.

Typically these sheets are adapted to be substantially irreversibly adhered together.

In a particularly preferred form of the invention, a cover sheet is adapted to be substantially irreversibly adhered to a base sheet arranged so that the biological sample may be positioned thereon. The cover sheet may be hingedly secured to the base sheet. In particular, the cover sheet may be coated with a permanent adhesive across its entire surface, and the portion of the

archived, will be readily apparent to the person analysing the sample.

According to a fifth aspect of the present invention, there is provided a device for collecting and storing a biological sample for subsequent analysis, comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

Typically said base sheet is adapted for a biological sample to be positioned on a first surface and has printing identifying the sample on a second surface. Typically the printing is a bar-code which encodes the animal tag identification code or the animal identification code itself. In the latter case, the code may be written into an appropriate space by the person taking the sample. Typically, the second surface also includes information as to how to use the sample collection device.

The base sheet is typically a substantially rectangular sheet of paper, hence the first surface is the obverse of said base sheet and the second surface is its reverse. Preferably, the base sheet is a gloss art paper to ensure strong adhesion, and it should not contain any chemicals which will inhibit or interfere with the analysis to be conducted. Typically it is a sheet of 150gsm A2 gloss art paper

Each substantially rectangular base sheet may be joined by a line of weakness to a substantially identical sheet in order to connect a plurality of devices in accordance with the present invention. This allows the devices to be provided to the user as a roll from which

the cover sheet, or at least in sufficient mutilation of the two for the attempt to tamper with a sample to be apparent.

An absorbent material may be secured on the front surface of said base sheet. This makes collection of body fluids easier as a quantity of these may be absorbed by the absorbent layer. Typically the absorbent layer is blotting paper.

According to a sixth aspect of the present invention, there is provided a method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

removing said backing sheet; and

allowing said cover sheet to adhere substantially irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

Devices in accordance with the present invention may also be supplied together with a sampling device for sampling animal tissue.

Accordingly in a seventh aspect of the present invention, there is provided a kit comprising a sample collection device as described above together with a sampling device.

The sampling device preferably takes a consistent and reproducible sample from animals whilst simultaneously avoiding any cross-contamination of tissue. The nature of the sampling device will be well understood by the person skilled in the art, but is typically forceps or pliers. The kit may also include instructions for use of the sample collection device.

CLAIMS

1. A device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample.

2. A device as claimed in claim 1 wherein said storage means comprises sheets of material suitable for digestion together with said biological sample, between which said biological sample is stored.

3. A device as claimed in claim 2 wherein said sheets are adapted to be substantially irreversibly adhered together.

4. A device as claimed in claim 3 wherein a cover sheet is adapted to be substantially irreversibly adhered to a base sheet arranged so that the biological sample may be positioned thereon.

5. A device as claimed in claim 4 wherein the cover sheet is hingedly secured to said base sheet.

6. A device as claimed in claim 5, further comprising a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

7. A device as claimed in claim 6 wherein the cover sheet is coated with a permanent adhesive across its entire surface, and the portion of the cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet.

8. A device as claimed in claim 7 wherein the adhesive is a pressure-sensitive adhesive.

9. A device as claimed in any one of claims 4 to 8 wherein said base sheet is printed on its reverse

10. A device as claimed in claim 9 wherein a bar code is printed on the reverse of said base sheet.

11. A device as claimed in any one of claims 4 to 10 wherein the base sheet is a sheet of paper.

12. A device as claimed in claim 11 wherein the base sheet is a sheet of gloss art paper.

13. A device as claimed in any one of claims 4 to 12 wherein the cover sheet is a clear polypropylene film.

14. A device as claimed in any one of claims of 6 to 13 wherein the backing sheet is a release paper.

15. A system for the analysis of a biological sample, comprising:

a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis;

means for taking at least a portion of said sample for analysis together with at least the part of said storage means in which it is encased;

means for digesting said sample, or portion thereof, together with at least said part of said storage means; and

means for analysing said sample.

16. A system as claimed in claim 15 wherein the device is a device as defined in any one of claims 1 to 14.

17. A system as claimed in claim 15 or claim 16 wherein a hole punch takes a portion of said sample for analysis together with that part of the storage means in which it is encased.

18. A system as claimed in any one of claims 15 to 17 wherein said sample is digested in an alkali extraction.

19. A system as claimed in any one of claims 15 to 18 wherein said sample is subjected to amplification by PCR and then DNA sequencing.

20. A method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample; and

storing said sample in said storage means.

21. A method as claimed in claim 20 wherein the device is a device as defined in any one of claims 1 to 14.

22. A method as claimed in claim 20 or claim 21 wherein said biological sample is stored for an extended period of time.

23. A method of analysing a biological sample, comprising the steps of:

providing a device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample;

taking at least a portion of said sample together with at least the part of said storage means in which it is encased;

digesting said sample, or portion thereof, together with at least said part of said storage means; and

analysing said sample.

24. A method as claimed in claim 23 wherein the device is a device as defined in any one of claims 1 to 14.

25. A method as claimed in claim 23 or claim 24 wherein a portion of said sample is punched out of the device with a hole punch.

26. A method as claimed in any one of claims 23 to 25 wherein said sample is digested in an alkali extraction.

27. A method according to any one of claims 23 to 26 wherein said sample is subjected to amplification by PCR and then DNA sequencing.

28. A device for collecting and storing a biological sample for subsequent analysis, comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

29. A device as claimed in claim 28 wherein said base sheet is printed on its reverse.

30. A device as claimed in claim 28 wherein a bar code is printed on the reverse of said base sheet.

31. A device as claimed in any one of claims 28 to 30 wherein the base sheet is a sheet of paper.

32. A device as claimed in claim 31 wherein the base sheet is a gloss art paper.

33. A device as claimed in any one of claims 28 to 32 wherein the cover sheet is coated with a permanent adhesive across its entire surface, and the portion of the cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet.

34. A device as claimed in claim 33 wherein the adhesive is a pressure-sensitive adhesive.

35. A device as claimed in any one of claims 28 to 34 wherein the cover sheet is a clear polypropylene film.

36. A device as claimed in any one of claims of 28 to 35 wherein the backing sheet is a release paper.

37. A method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

removing said backing sheet; and

allowing said cover sheet to adhere substantially irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

38. A kit comprising a sample collection device as defined in any one of claims 1 to 14 and a sampling device for collecting a biological sample.